Remarks

Reconsideration of this application is respectfully requested in view of the above amendment and the following remarks.

Claims 21-23, 25-27 and 29 are pending in the application. Claims 21-23, 25-27 and 29 have been rejected. Claims 21, 23 and 27 have been amended. It is noted that the specification has been amended on page 4, line 6 to correct a minor typographical error. Specifically "bottle 3" has been replaced with "bottle 2". No new matter has been added.

Claim 21 has been rejected under 35 U.S.C. §112, second paragraph, as being indefinite. In particular, the Examiner stated "The wording of claim 21 is confusing as it cannot be determined whether the "tube comprising a laminated polypropylene foil" has a cap."

In response, Claim 21 has been amended to recite "tube comprising a laminated polypropylene foil with a cap and a polypropylene bottle with a cap...". While the specification does not specifically recite that the tube has a cap, Applicants assert that it is clear from the recitation in Claim 21 of "a closed squeezable pharmaceutical package" which is selected from a tube comprising a laminated polypropylene foil and polypropylene bottle that the tube would possess a cap. In addition, the specification, in its description that a tube containing ophthalmic pharmaceutical solutions and gels can be sterilized as a whole after filling the product into the package by an autoclaving process, also makes clear that the filled tube would possess a cap (see, e.g., page 6, paragraph 3).

In view of the above, withdrawal of the rejection of Claim 21 under 35 U.S.C. §112, second paragraph, is respectfully requested.

Before addressing the next rejection, it is further noted that Claim 23 has been amended to recite "the polypropylene bottle..." and Claim 27 has been amended to recite "wherein the polypropylene bottle...".

Claims 21-22, 25-26 and 29 have been rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,052,558 (Carter) in view of U.S. Patent No. 5,460,283 (MaCartney et al.).

In particular, the Examiner stated:

> "With respect to claims 21, 22, 26, Carter discloses a method of packaging and steam sterilizing a pharmaceutical product such as saline solution (col. 2, lines 62-67). A semi-rigid squeezable polypropylene bottle **20** is filled with a pharmaceutical product and one the bottles are sealed and prepared for sterilization, they are inserted into an autoclave. See col. 4, lines 47-60. The

> autoclaved sterilized the bottles using an application of steam at temperatures of 121°C. Although Carter teaches that the bottles **20** and caps **22** are "preferably made of a polypropylene material...it is recognized that there are other polymeric materials which might be suitable... See Col. 2, lines 54-62. Carter does not specifically teach forming the cap from a material with a modulus of elasticity different from polypropylene.
>
> MaCartney et al. discloses a polyethylene cap for use with container, particularly polypropylene containers. MaCartney et al. teaches that polypropylene container and caps have the inherent characteristic of "drawing back" at the point of contact, thereby reducing the contact pressure at the seal interface and impairing or destroying the integrity of the seal. See. Col. 1, lines 42-48. As a solution, MaCartney et al. proposes using a stiff polyethylene cap for the polypropylene bottle, which maintains long term sealing engagement between the sealing surfaces. See col. 2, lines 64-67 and col. 4, lines 35-39. As Carter recognizes the expansion and contraction of polypropylene during sterilization and the subsequent relaxing of the seal (col. 3, lines 42-46), it would have been obvious to one of ordinary skill in the art to replace the polypropylene cap of Carter with a polyethylene cap for the reasons disclosed by MaCartney et al."

Applicants disagree with the Examiner's conclusion and respectfully submit that the combined cited references do not make obvious the claimed subject matter as defined in independent Claims 21 and 26 for the reasons stated below.

At the outset, it is noted that the Examiner bears the initial burden of proving a *prima facie* case of obviousness. This burden can be met by showing some objective teaching in the prior art or that knowledge that is available to one of ordinary skill in the art would motivate that individual to combine the relevant teachings of the references. In re Fritch, 972 F.2d 1260, 1265, 23 U.S.P.Q. 2d 1780, 1783 (Fed. Cir. 1992) [citing In re Piasecki, 745 F.2d 1468, 1471-72, 223 U.S.P.Q. 785, 787-88 (Fed. Cir. 1984)]. The Applicant can rebut the Examiner's *prima facie* case of obviousness by showing it was improperly made out, or by providing objective evidence which supports a conclusion of non-obviousness. *Id.* at 1265 citing In re Heldt, 433 F.2d 808, 811, 167 U.S.P.Q. 676, 678 (CCPA 1970).

With particular relevance to the present application, MPEP §2141 (Basic Considerations Which Apply to Obviousness Rejections) states *inter alia*:

> "When applying 35 U.S.C. §103, the following tenets of patent law must be adhered to:
>
> (A) The claimed invention must be considered as a whole; and
>
> (B) The references must be considered as a whole and must suggest the desirability and thus the obviousness of making the combination..."

It is asserted that the cited references when considered as a whole do not suggest the desirability and thus the obviousness of replacing a polypropylene cap with a polyethylene cap on a filled polypropylene bottle subjected to an autoclaving process.

In considering the presently claimed pharmaceutical package and the teachings of Carter and MaCartney et al. the Examiner's attention is directed to MPEP §2141.02 which indicates that when ascertaining the differences between the prior art and the claims at issue, not only must the claimed invention be considered as a whole, but also the prior art reference must be considered in its entirety, i.e., as a whole,....

With respect to Carter, the Examiner has not considered the teachings pertaining to Carter's container in its entirety as is evidenced by the Examiner's omission of an important component of Carter's capped container as is discussed below.

Carter is directed to a method of filling and sterilizing an improved squeeze-type bottle which is packaged in a blister pack prior to being subjected to a steam-sterilized procedure. The improved process involves the use of a bottle and cap, preferably formed of polypropylene (see column 1, lines 60 and column 2, lines 56-60). Carter indicates that there are other materials which might be suitable for the bottles and the caps (see column 2, lines 59-62). Carter, however, fails to teach or specifically suggest that the caps can be made of a material with a modulus of elasticity different from polypropylene. Carter also indicates that one of the novel steps in the process is the introduction of a silicone gasket or washer which is inserted into the threaded screw-type cap such that the gasket is positioned between the cap and the bottle top to absorb pressures which develop by expansion of the bottle and/or the cap (see column 1, lines 62-66). In particular with respect to the function of the gasket, Carter states:

> "The silicone gasket prevents any deformation of the cap, of the cannula adapter, or the bottle, and substantially eliminates any leakage of the sterile fluid from the bottle during sterilizing." (see column 1, lines 66-68 and column 2, line 1; see also column 3, lines 47-51)..."

Carter further indicates that in previous processes it was found that the polypropylene undergoes significant expansion and contraction during the sterilization process increasing the likelihood of loose caps and leakage of material out of the bottle at the end of the processing (see column 3, lines 42-46). That the gasket is an important component of Carter's package and provides a solution to the problem of loose caps and leakage out of the bottle which is encountered when sterilizing the polypropylene bottle is further indicated by Carter's statement:

> "The introduction of the rubber gasket between the screw-cap and the bottle absorbs pressures developed by expansion and contraction and prevents deformation of the cap 22, the cannula adapter 40, or the bottle 30 and substantially eliminates any problems with leakage."

Thus, Carter successfully solves the problem of loose caps and leakage that is encountered when sterilizing polypropylene bottles having polypropylene caps by utilizing a gasket that is positioned between the cap and bottle. Carter does not teach or specifically suggest that such a problem can also be solved by replacing a polypropylene cap with a polyethylene cap. Indeed, one skilled in the art reading Carter would not be motivated to consult another reference to offer a different solution to the problem of loose caps and leakage out of the bottle, since Carter has already provided a successful solution to this problem.

Further, in arriving at the present invention, the inventors were not concerned with the particular problem encountered by Carter in sterilizing the polypropylene bottle, i.e., loose caps and leakage (impairment of the seal). Instead, the inventors of the present invention were concerned with the problem of sealing between a nozzle tip of a polypropylene bottle, particularly a nozzle tip formed of polypropylene, and a cap also formed of polypropylene when the polypropylene bottle was sterilized. In this regard, the Examiner's attention is directed to the present specification on page 4, first paragraph, lines 13-21, wherein it states:

> "The nozzle tip is also particularly formed of a specific form of polypropylene, particular a polypropylene of the type Appryl 3020 SM3. There occur no problems during the autoclaving processing which could generate leakage problems. Rather, by using the same material for the bottle 3 and the nozzle tip 3 the two components are sealed a little bit together during the autoclaving process...The cap 5 as the closure of the bottle assembly is particularly formed of a high density polyethylene, particularly of HDPE GC7260. The cap 5 can also be made of polypropylene, however in this case during the autoclaving processing a sealing between the nozzle tip 3 and the cap 5 can occur, so that it is quite difficult to open the bottle 2 or the nozzle tip 3 is damaged after opening of the bottle 2. [emphasis added with underlining] If the cap 5 is made of another material than polypropylene, the risk of a sealing or other damages can be avoided as these two materials have a different modulus of elasticity."

Accordingly, one skilled in the art would not utilize Carter to solve the problem of sealing between the nozzle tip and cap since Carter was concerned with the problem of leakage and loose caps.

In sum, Carter as a whole: 1) fails to teach or specifically suggest use of a polyethylene cap or the desirability of replacing a polypropylene cap with a polyethylene cap; 2) successfully solves the problem of loose caps and leakage that is encountered when sterilizing polypropylene bottles with caps formed of polypropylene by utilizing a gasket which is positioned between the bottle and cap; and 3) fails to be concerned with the problem of sealing of a nozzle tip with a cap upon sterilization of a polypropylene bottle.

With respect to MaCartney et al., the Examiner has not considered the teachings pertaining to the MaCartney et al. container in its entirety as is evidenced by the Examiner's lack of concern that MaCartney et al. provides a solution to a problem different from the problem that was faced by the inventors of the present invention as is discussed below.

MaCartney et al. is directed to containers used to hold infectious and carcinogenic material and is concerned with the problem encountered when such filled containers are made of polypropylene. In particular, MaCartney et al. indicate that polypropylene has the inherent characteristic of "drawing back" at the point of contact, thereby reducing the contact pressure at the seal interface and impairing or destroying the integrity of the seal. To solve this problem of "drawing back", MaCartney et al. uses a polypropylene container with a rim seal closure cap, wherein the cap is made of a stiff polyethylene cap to maintain long term sealing engagement between the sealing surfaces. Accordingly, MaCartney et al., is not concerned with the problem of sterilization of a closed squeezable package, but is merely concerned with preventing leakage of infectious or carcinogenic materials. Indeed, one skilled in the art would not utilize this reference in combination with Carter as the problem faced in MaCartney et al., i.e., drawing back of the seal which impaired or destroyed integrity of the seal and led to leakage was a completely different problem than the problem faced by the present inventors in sterilizing a squeezable pharmaceutical package, i.e., the problem of sealing between the nozzle tip and the cap.

In sum, MaCartney et al. as a whole is concerned with the problem of "relaxing" of the polypropylene container rim over time and subsequent leakage from the bottle of infectious or carcinogenic material, whereas the present invention was concerned with the problem of sealing between a nozzle tip and cap upon sterilization of a polypropylene bottle having a nozzle tip and a cap. Accordingly, since MaCartney et al. was concerned with solving a problem that was different from the problem faced by the present inventors, one skilled in the art would not be motivated to combine MaCartney et al. with Carter to provide a solution to the problem faced by the inventors of the present invention.

Thus, since Carter alone or combined with MaCartney et al. does not suggest the desirability of replacing a polypropylene cap with a polyethylene cap to solve the problem of sealing of the nozzle tip and cap when sterilizing a polypropylene bottle, Carter alone or combined with MaCartney et al. does not make obvious the presently claimed invention.

In view of the above, withdrawal of the rejection of Claims 21-23, 25-27 and 29 under 35 U.S.C. §103 is respectfully requested.

A good faith effort has been made to place this application in condition for allowance. If the Examiner believes that a telephone conference would be of value, he is requested to call the undersigned counsel at the number listed below.

Respectfully submitted,

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